

## **REMARKS**

### **Interview Summary**

Applicants thank Examiner Navarro for the courtesy extended during the telephonic interview on April 28, 2010. During the interview Applicants representative, Lou Lieto, and Examiner Navarro discussed proposed amendments to the claims in view of the prior Office Action.

### **I. Amendments to the Specification**

Applicants' amendments to the specification correct obvious spelling errors; therefore, Applicants submit that no new matter is introduced.

### **II. Status of the claims**

In response to the Office Action dated November 9, 2010, Applicants respectfully request consideration of the claims provided herein. Claims 2, 37, 48, and 64 are pending. Claims 1, 7, 36, 38, 45-47, 49, 56-58, 62, 63, and 65-67 are amended. Claims 3-6, 8-29, and 59-61 are canceled. Claims 68-73 are new. Claims 30-35, 39-44, 50-55 and 68-73 are withdrawn. Following the amendments, claims 1, 2, 7, 36-38, 45-49, and 56-58, 62-67 are pending in the current application.

### **III. Support for the amendments**

The amendments provided herein do not constitute new matter. Support for the amended and new claims can be found in the claims and specification as filed including, *inter alia*, in the claims as originally filed. Cancellation of any subject matter herein does not constitute an admission that the subject matter is unpatentable for any reason. Applicants submit that no new matter has been introduced. Reference is made to published version of the specification, US PGPUB 20020081628.

For example, basis for the amended claims can be found throughout the specification. For example as follows:

Claims 1, 36, and 47: paragraphs 3, 15, 16, 22, 23, and 39;

Claims 34, 43, and 54: paragraphs 15, 16, 22, and 39;

Claims 35, 44, and 55: paragraphs 22 and 39.;

Claims 45 and 46: paragraphs 22 and 39;

Claims 56, 57, and 58: paragraph 25.

#### **IV. Priority**

The Examiner has alleged that the claims which recite *Campylobacter* and *Clostridiuim difficile* are only entitled to a priority date of November 16, 2001. Applicants disagree. However, solely to expedite prosecution, subject matter relevant to *Campylobacter* and *Clostridiuim difficile* has been canceled from the claims. Applicants submit that the pending claims are entitled to the earliest claimed priority date of November 16, 2000. Applicants respectfully request that the Examiner acknowledge that the claims are entitled to their earliest claimed priority date.

#### **V. Rejection under 35 USC § 112, first paragraph**

Claim 1, 2, 7, 36-38, 45-49, and 56-67 stands rejected under 35 U.S.C. § 112, first paragraph because the specification while enabling for diagnosing autism, by detecting the presence of antigens from a plurality of pathogens listed...together with measuring abnormally low levels of chymotrypsin, allegedly does not reasonably provide enablement for method of diagnosis by detecting antigens of a plurality pathogens. (Office action, pages 3-4.)

Applicants respectfully traverse the rejection and submit that the claims are enabled for their full scope. Solely to expedite prosecution, Applicants note that independent claims 1, 36 and 47 have been amended to recite in part: "analyzing the stool sample to detect the level of chymotrypsin present." Further the independent claims recite that a determination or diagnosis is made based on "on the presence of the one or more antigens associated with the two or more different pathogens and an abnormally low level of chymotrypsin in the stool sample."

Applicants submit that claims 1, 36, 47, and their dependents correspond are fully enabled by the specification and respectfully request that the rejection be withdrawn.

## **VI. Rejections under 35 USC § 112, second paragraph**

Claims 56-61 and 65-67 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly being incomplete for omitting essential steps, such omission amounting to a gap between the steps. The Office asserts:

the omitted steps are: -----measuring chymotrypsin digestive enzyme levels in a sample from said individual, and administering to said individual a composition comprising chymotrypsin when chymotrypsin levels are abnormally low. *Office action, page 6.*

In addition to the amendments described above, Applicants have also amended claims 56-58, solely to clarify the claim language. Claims 56-58 presently recite, in part: “further comprising treating an individual determined to have Autism by administering one or more digestive enzymes comprising chymotrypsin.” Claims 59-61 are canceled. Claims 65-67 depend from claims 56-58. Applicants submit the pending claims are no longer incomplete and respectfully request that the rejection be withdrawn.

## **VII. Rejection under 35 USC § 102**

Claims 1, 2, 7, 45, 47-49 stand rejected under 35 U.S.C. 102(a) as allegedly being unpatentable over WO01/27612 (publication date April 19, 2001)(Reiter) in light of the English translation provided by US Patent 7,129,053.

Applicants submit that the Reiter reference no longer qualifies as art under 102(a) as the claims are entitled to the priority date of November 16, 2000. Applicants respectfully request that the rejection over the cited art be withdrawn.

Claims 1-2, 36-37, 45-46, 47, 48, 62-64 stand rejected under 35 U.S.C. 102(e) as allegedly being unpatentable over US PG-Pub 2008/0254009 (Feinberg).

Applicants respectfully traverse the rejection. Solely to expedite prosecution, Applicants note that independent claim 1, 36 and 47 have been amended to recite in part: “analyzing the stool sample to detect the level of chymotrypsin present.” Further the independent claims recite that a determination or diagnosis is made based on “on the

presence of the two or more antigens associated with the one or more different pathogens and an abnormally low level of chymotrypsin in the stool sample.”

All other rejected claims depend from claims 1, 36, or 47. Applicants submit that Feinberg does not disclose analyzing the stool sample to detect the level of chymotrypsin and therefore does not anticipate the claims. Applicants respectfully request that the rejection over the cited art be withdrawn.

#### **VIII. Rejoinder of Restricted Species**

Upon the finding of patentable claims to the elected Species, Applicants respectfully request rejoinder of claims drawn to the pending unelected species (Claims 30-35, 39-44, 50-55, and 68-73). Applicants note that these claims have been amended in a manner corresponding to the claims under examination.

**CONCLUSION**

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415, referencing Attorney Docket 41012-705.201. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned attorney with any questions or to otherwise expedite prosecution.

Further, none of Applicants' amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Respectfully submitted,

Dated: May 4, 2011

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